HFI-55

DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

M2358n

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

February 4, 1999

WARNING LETTER NYK 1999-30

Donald R. Lynch, President and Chief Executive Officer
LORS Medical Corporation
544 Weldon Road
Roanoke Rapids, North Carolina 27870

Dear Mr. Lynch:

During an inspection of your medical gas manufacturing facility located at 6466 Ridings Road, Syracuse, New York, conducted on December 16 - 21, 1998, our investigator documented deviations from the Current Good Manufacturing Practice regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 and 211). These deviations cause your drug product, Oxygen, Refrigerated Liquid, USP (ORL), to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The deviations noted by the investigator include, but are not limited to, the following:

1. Failure to retest ORL in home vessels for identity after repair of home vessels as required by 21 CFR 211.87. For example, ORL in home vessels with serial numbers G-013C91 and 61765105 were not tested for identity prior to distribution after these vessels were repaired and returned by your North Carolina facility and subsequently filled at the New York facility.

2. Failure of batch production records to include complete and accurate information relating to the production and control of each batch of ORL as required by 21 CFR 211.188. For example, the Daily Filling Record and Calibration Log dated 12/15/98 incorrectly documents the ORL lot number as 121598-1 when the correct lot number is 121598-4.

3. Failure to establish and follow adequate written procedures to assure correct labels and labeling are used for drug products as required by 21 CFR 211.122 and 211.130. For example, current Standard Operating Procedures do not address the receipt, examination and storage of ORL labels.

4. Failure to always obtain a Certificate of Analysis (COA) from the supplier for bulk ORL in lieu of performing testing to determine conformance with appropriate specifications for identity and strength as required by 21 CFR 211.165(a). Review of your records revealed no COA for bulk ORL lot #111998-1 used to fill home vessels on 11/23/98.

Your product is also misbranded because its container lacks labeling required by Section 502 of the Act. Such labeling must include, for example, a statement of the quantity of contents [502(b)(2)], the address of the manufacturer [502(b)(1)], and a statement indicating whether or not the oxygen was produced by the air-liquefaction process as required by the United States Pharmacopoeia (USP XXIII) [502(g)].

In addition, the Center for Drug Evaluation and Research (CDER) has no record indicating your firm is in compliance with Section 510(j) of the Act. Section 510(j) requires your firm not only to list its drug products, but also to submit a copy of all labeling for each product to the FDA. Such labeling should be made part of the Master Control Record to assure correct labeling of home ORL vessels. I have enclosed an instruction booklet regarding registration and listing procedures and the necessary forms needed to facilitate your compliance with these requirements.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure all drugs manufactured and distributed by your firm meet the requirements of the Act, and the regulations promulgated thereunder. Federal agencies are advised of all warning letters regarding drug products so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to correct these deviations may result in regulatory action without further notice. Possible regulatory actions include seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Your response should be directed to Lisa M. Utz, Compliance Officer, at the above address. If you require further information, you may contact Mrs. Utz by telephone at (716) 551-4461, ext. 3165.

Sincerely,

Brenda J. Holman
District Director

Enclosure